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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HELMER, GEORGIA L	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,113	DING, SHOU-WEI	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,26,30 and 32-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,26,30 and 32-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *17 Sept 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 September 2004 has been entered.

Status of the Claims

2. Applicant has cancelled claims 25 and 31. Applicant has amended claims 24, 26, 30, 32, 33, and 35-36, and added new claims 38-43. Claims 24, 26, 30, and 32-43 are pending, and are examined in the instant action.

3. All rejections not addressed below have been withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

5. The Office acknowledges receipt of Applicant's Information Disclosure Statement (PTO-1449), filed 17 September 2004. A signed copy is enclosed.

Claim Rejections - 35 USC § 112-second

6. Claims 24, 26, 30, and 32-43 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 24, line 6, the phrase "and the cell death domain of the Cmv2b gene" is confusing because line 3 refers to a "C-terminal inactive cell death domain". Is the cell death domain of the Cmv2b active or inactive?

Claim Rejections - 35 USC § 112, first paragraph

Written description

7. Claims 24, 26, 30, and 32-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record, which are reiterated below:

Claim 24 is drawn to a transgenic plant stably transformed with DNA that encodes a protein, wherein the two domains are an N-terminal resistance domain and a C-terminal inactive cell death domain, wherein N-terminal resistance domain is the resistance domain of the Tav2b gene, said C-terminal inactive cell death domain is selected from the groups consisting of an inactive cell death domain of the Tav2b gene and the cell death domain of the Cmv2b, and said DNA sequence is operatively linked to a promoter capable of causing expression of said DNA sequence in said plant when said plant is infected with a pathogenic organism.

Claim 26 is drawn to the C-terminal inactive cell death domain is the cell death domain of the Cmv2b gene.

Claim 30 is drawn to an expression vector comprising a DNA sequence that encodes a protein comprising two domains are an N-terminal resistance domain and a C-terminal inactive cell death domain, wherein N-terminal resistance domain is the resistance domain of the Tav2b gene, said C-terminal inactive cell death domain is selected from the groups consisting of an inactive cell death domain of the Tav2b gene and the cell death domain of the Cmv2b, said DNA sequence is operatively linked to a plant active promoter .

Applicant traverses saying primarily that the Tav2b gene has been fully described in the specification, citing specifics (Response, p. 8). Applicant's traversal is unpersuasive. The cited material, (p. 11 line 25 – p. 12 line 1, and Examples 2, 7-11) recites the "N-terminal region of 69 amino acids of Tav2b". Example 1 (Response, p. 17 lines 1-5) refers to the coding sequence of the Tav2b gene (SEQ ID NO: 1, encoding 95 amino acids). This description is represented by SEQ ID NO:1 , therefore the SEQ ID NO:1 needs to be set forth in the claims.

Applicant traverses saying primarily that the cell death domain of the Tav2b and Cmv2b genes have been fully described in the specification, citing specifics (Response, p. 8). Applicant's traversal is unpersuasive. The cited material, (p. 12 line 1, p. 13 lines 23 and Examples 7-11) recites the "the amino acids 70-9 of Tav2b". Example 1 (Response, p. 17 lines 1-5) refers to the coding sequence of the Tav2b gene (SEQ ID NO: 1, encoding 95 amino acids). This description is represented by SEQ ID NO:1 , therefore the SEQ ID NO:1 needs to be set forth in the claims.

Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.ed 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have recognized Applicants to have been in possession of the genus claimed at the time this application was filed.

Claim Rejections - 35 USC § 112-Enablement

8. Claims 24, 26, 30, and 32-43 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicant's claims 24, 26, 30, and 32-43 are drawn to polynucleotides which are not appropriately described to fulfill the 112.1 Written Description requirement, and would not have been in possession of the genus claimed at the time this application. Since the claimed invention lack written description, it would not be possible for one skilled in the art to make and use the invention.

9. Claims 24, 26, 30, and 32-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

The breadth of the claims and the nature of the invention:

The claims are drawn to a transgenic plant stably transformed with DNA that encodes a protein, wherein the two domains are an N-terminal resistance domain and a C-terminal inactive cell death domain, wherein N-terminal resistance domain is the resistance domain of the Tav2b gene, said C-terminal inactive cell death domain is selected from the groups consisting of an inactive cell death domain of the Tav2b gene and the cell death domain of the Cmv2b, and said DNA sequence is operatively linked to a promoter capable of causing expression of said DNA sequence in said plant when said plant is infected with a pathogenic organism. Further claims are drawn to an expression vector comprising a DNA sequence that encodes a protein comprising two domains are an N-terminal resistance domain and a C-terminal inactive cell death domain, wherein N-terminal resistance domain is the resistance domain of the Tav2b gene, said C-terminal inactive cell death domain is selected from the groups consisting of an inactive cell death domain of the Tav2b gene and the cell death domain of the Cmv2b, said DNA sequence is operatively linked to a plant active promoter. Further claims are drawn to plants, seeds and plant propagules.

The predictability or lack thereof in the art: Applicant traverses the unpredictability as set forth in the Office Action of 12 February 2003, saying (Response of 14 July 2003, p. 9 and 10) that the Agrios reference does not support Examiner's statement. The 12 Feb 2003 Office Action is repeated in part below:

The enablement issues are: expression of the two-domain gene under control of a promoter activated by infection with a plant pathogen, any pathogenic organism, and transgenic plants other than tomato and tobacco.

The results of infecting a given plant with a given plant pathogen are unpredictable. It is known in the art that the host range of plant pathogens varies. Pathogens vary with respect to the kinds of plants they can attack, with respect to the organs and tissues that they can infect, and with respect to the age of the organ or tissue of the plant on which they can grow (Agrios, G.N. Plant Pathology, 3rd edition, 1988, Academic Press, San Diego; p 43). Different types of plant resistance to pathogens exist. Plants are resistant to certain pathogens either because they belong to taxonomic groups that are immune to these pathogens or because they possess genes for resistance directed against the genes for virulence of the pathogen, or because for various reasons, the plants escape or tolerate infection by these pathogens (Agrios, p124).

Applicant teaches a two-domain Avr gene comprising a both the resistance domain of the Tav2b gene and the cell death domain of the Cmv2b gene, under the control of the U1 sgRNA promoter of TMV (Example 8, p28). Applicant further teaches that PR proteins are induced in wild-type tobacco following inoculation with a TMV-2vb virus.

- There is no teaching of the two-domain Avr gene under the control of a plant pathogen activated promoter. (End of citation from previous Office Action)

Applicant traverses saying primarily that the Agrios reference simply states what is well know in the art (Response of July 2003). Applicant acknowledges further that there is a wide variety of plant pathogens that attack plants in a wide variety of ways and that

often pathogens are plant or even tissue specific, that this does not indicate unpredictability in the art. Applicant further sets forth that screening plants against known pathogens is a long-standing and routine practice (Response, p. 9-10). Applicant's traversal is unpersuasive. The mere germ of an idea does not constitute an enabling disclosure, and the specification, not the knowledge of one skilled in the art must supply the enabling aspects of the invention. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2nd 1001, 1005 (Fed. Cir. 1997).

Amount of Guidance and the presence of working examples or lack of working examples:

Applicant teaches a two-domain gene comprising a both the resistance domain of the Tav2b gene and the cell death domain of the Cmv2b gene, under the control of the U1 sgRNA promoter of TMV (Example 8, p28). Applicant further teaches that PR proteins are induced in wild-type tobacco following inoculation with a TMV-2vb virus. There is no teaching of the claimed two-domain gene being expressed under the control of a plant pathogen activated promoter.

Applicant traverses saying primarily that they have shown that "the invention functions" in three different plant species and two different genera (Response, p. 12), specifically Applicant have shown activity in Nicotiana asnathum, X. Benthamiana and Physali floridana. Applicant's traversal is unpersuasive. The claims are drawn to a transgenic plant stably transformed with DNA that encodes a protein, wherein the two domains are an N-terminal resistance domain and a C-terminal inactive cell death domain, wherein N-terminal resistance domain is the resistance domain of the Tav2b

gene, said C-terminal inactive cell death domain is selected from the groups consisting of an inactive cell death domain of the Tav2b gene and the cell death domain of the Cmv2b, and said DNA sequence is operatively linked to a promoter capable of causing expression of said DNA sequence in said plant when said plant is infected with a pathogenic organism Applicant teaches the two-domain gene comprising a both the resistance domain of the Tav2b gene and the cell death domain of the Cmv2b gene, under the control of the U1 sgRNA promoter of TMV (Example 8, p28). Applicant further teaches that PR proteins are induced in wild-type tobacco following inoculation with a TMV-2vb virus. There is no teaching of the two-domain gene under the control of a plant pathogen activated promoter.

Amount of Experimentation necessary. Undue trial and error experimentation would be required to screen through and identify which transgenic plant of all plant hosts, including redwoods, maize, and duckweed, of what age, development stage and tissue specificity, if any, and which pathogenic organism, of all plant pathogens including bacteria, fungi, and viruses would function as desired in stable transformation with the transgenic plant with DNA that encodes a protein, wherein the two domains are an N-terminal resistance domain and a C-terminal inactive cell death domain, wherein N-terminal resistance domain is the resistance (what is the resistance to?) domain of the Tav2b gene (what Tav2b gene, having what sequence, of such size, and all Tav viruses identical, or are there naturally occurring variants?), said C-terminal inactive cell death domain is selected from the groups consisting of an inactive cell death domain of the Tav2b gene (what Tav2b gene, having what sequence, of such size, and what is the

"inactive" relative to because there is not teaching of "active"), and the cell death domain of the Cmv2b (what Cmv2b gene, having what sequence, of such size, and are all Cmv viruses identical, or are there biological variants naturally occurring?), and said DNA sequence is operatively linked to a promoter capable of causing expression of said DNA sequence in said plant when said plant is infected with a pathogenic organism. A myriad of experimentation involving cascade of experiments one dependent on the other would be required to screen through and identify what "plant active promoter" from what plant, giving what kind of "activity" would function as desired with the expression vector of DNA that encodes a protein, wherein the two domains are an N-terminal resistance domain and a C-terminal inactive cell death domain, wherein N-terminal resistance domain is the resistance (what is the resistance to?) domain of the Tav2b gene (what Tav2b gene, having what sequence, of such size, and all Tav viruses identical, or are there naturally occurring variants?), said C-terminal inactive cell death domain is selected from the groups consisting of an inactive cell death domain of the Tav2b gene (what Tav2b gene, having what sequence, of such size, and what is the "inactive" relative to because there is not teaching of "active"), and the cell death domain of the Cmv2b (what Cmv2b gene, having what sequence, of such size, and are all Cmv viruses identical, or are there biological variants naturally occurring?)

While one working example may enable a broader scope, Applicant has not provided a single working example of the two-domain gene under the control of a plant pathogen activated promoter. Applicant recites a viral subgenomic promoter but claims any promoter capable of causing expression in the plant when the plant is infected any

pathogenic organism. Applicant has given no evidence that any such promoter would be able to express the DNA of interest in the plant material, transiently of otherwise. While working examples are not required, Applicant must provide sufficient guidance to address all these issues. Without such guidance, the experimentation required would not be routine, but would be undue.

Remarks

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Art Group 1638
November 29, 2004

ELIZABETH MCELWAIN
PRIMARY EXAMINER